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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,609	02/21/2002	Stefan Kochanek	50125/020002	7269

7590 11/28/2003

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,609	KOCHANEK ET AL.	
	Examin r	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-21 are pending.

Election/Restrictions

Restriction to one of the following inventions is required and an election of species is required under 35 U.S.C. 121:

I. Claims 2 and 3, drawn to a retinal pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding a neurotrophic factor, classifiable in class 424, subclass 93.21.

II. Claims 2 and 3, drawn to a retinal pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding an anti-angiogenetic factor, classifiable in class 424, subclass 93.21.

III. Claims 2 and 3, drawn to a retinal pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding an anti-oxidative factor, classifiable in class 424, subclass 93.21.

IV. Claims 2 and 3, drawn to a retinal pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding a lysosomal factor, classifiable in class 424, subclass 93.21.

V. Claims 2 and 3, drawn to a retinal pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding a vasodilating factor such as NO synthase, classifiable in class 424, subclass 93.21.

VI. Claims 2 and 3, drawn to an iris pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding a neurotrophic factor, classifiable in class 424, subclass 93.21.

VII. Claims 2 and 3, drawn to an iris pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding an anti-angiogenetic factor, classifiable in class 424, subclass 93.21.

VIII. Claims 2 and 3, drawn to an iris pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding an anti-oxidative factor, classifiable in class 424, subclass 93.21.

IX. Claims 2 and 3, drawn to an iris pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding a lysosomal factor, classifiable in class 424, subclass 93.21.

X. Claims 2 and 3, drawn to an iris pigment epithelial cell of the eye, which comprises an adenoviral vector comprising a nucleic acid encoding a vasodilating factor such as NO synthase, classifiable in class 424, subclass 93.21.

XI. Claims 7 and 11, drawn to a fixed assemblage of pigment epithelial cell of the eye, classifiable in class 435, subclass 395.

XII. Claims 8 and 12, drawn to cultivation system comprising at least one pigment epithelial cell of the eye and a feeder layer, class 435, subclass 373.

XIII. Claim 13, drawn to a method of treating AMD comprising administering the pigment epithelial cell of claim 1, classifiable in class 424, subclass 93.21.

XIV. Claim 13, drawn to a method of treating glaucoma comprising administering the pigment epithelial cell of claim 1, classifiable in class 424, subclass 93.21.

XV. Claim 13, drawn to a method of treating a diabetic retinopathy comprising administering the pigment epithelial cell of claim 1, classifiable in class 424, subclass 93.21.

XVI. Claim 13, drawn to a method of treating a genetic disease of the pigment epithelium comprising administering the pigment epithelial cell of claim 1, classifiable in class 424, subclass 93.21.

XVII. Claim 14, drawn to a method of treating an AMD comprising administering the fixed assemblage of cells of claim 7, classifiable in class 424, subclass 93.1.

XVIII. Claim 14, drawn to a method of treating a glaucoma comprising administering the fixed assemblage of cells of claim 7, classifiable in class 424, subclass 93.1.

XIX. Claim 14, drawn to a method of treating a diabetic retinopathy comprising administering the fixed assemblage of cells of claim 7, classifiable in class 424, subclass 93.1.

XX. Claim 14, drawn to a method of treating a genetic disease of the pigment epithelium comprising administering fixed assemblage of cells of claim 7, classifiable in class 424, subclass 93.1.

XXI. Claims 16, 17, 18 and 20, drawn to a method of treating Parkinson's Disease comprising using a pigment epithelial cell, classifiable in class 424, subclass 93.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function and different effects. Inventions I-V are directed to a retinal pigment epithelial cell and Inventions VI-X directed to an iris pigment epithelial cell. The neurotrophic factor in Inventions I and VI; the anti-angiogenetic factor in Inventions II and VII; the antioxidative factors in Inventions III and VIII; the lysosomal factor in Inventions IV and IX; and the vasodilating factor in Inventions V and X have a different mode of operation, different function, and different effect. The fixed assemblage of cells in Invention XI has a different function and different effect then the genetically modified cells in Inventions I-X because the fixed assemblage of cells does not contain an adenoviral vector in the cells. The cultivation system in Invention XII has a different mode of operation, different effect and different function then Inventions I-XI because the cultivation system contains a feeder layer and does not contain an adenoviral vector. The cultivation system in Invention XII has a different mode of operation than the fixed assemblage of cells in Invention XI because the system contains a feeder layer. The specification does not disclose that the inventions are capable of use together.

Invention I-X and Inventions XIII-XVI and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product in inventions I-X can be

used in materially different processes as set forth in Inventions XIII-XVI and XXI. The processes in Inventions XIII-XVI and XXI are materially different because each invention uses different patients suffering from a different disease.

Invention XI and Inventions XVII-XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product in Invention XI can be used in materially different processes as set forth in Invention XVII-XX. The processes in Inventions XVII-XX are materially different because each invention uses different patients suffering from a different disease.

Inventions XIII-XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function and different effects. Each method in inventions XIII-XXI has a different mode of operation, different function, different effect. The diseases in Inventions XIII-XXI are materially different because each invention uses different patients suffering from a different disease. The gene used for one disease is not likely to be the same gene used for different diseases. Inventions XIII-XVI use the cell as a means for delivering a therapeutic nucleic acid and the property of the cell not a therapeutic nucleic acid provides the primary therapeutic in Inventions XVII-XXI. The specification does not disclose that the inventions are capable of use together.

Claims 1, 3, 4, 5, 6, 9, 10, and 21 link(s) inventions I-X. Claim 2 separately links inventions I-V to each other, and links inventions VI-X to each other. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 2, 3, 4, 5, 6, 9, 10, and 21. Claims 13, 15, and 19 link(s) inventions XIII-XVI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 13, 15, and 19. Claim 14, 15, and 19 link(s) inventions XVII-XX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 14, 15, and 19. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

If applicants elect either Group I or Group VI, this application contains claims directed to the following patentably distinct species of the claimed invention: neurotrophic factor selected

from GDNF, PEDF, NGF, BDNF, CNTF, bFGF, neurotrophin 3, neurotrophin 4, or neurotrophin 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 3 is generic.

If applicants elects either Group II or Group VII, this application contains claims directed to the following patentably distinct species of the claimed invention: anti-angiogenetic factor selected from soluble VEGF receptor-1 (sflt-1), a dominant-negative VEGF receptor-2 (KDR) or PEDF.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 3 is generic.

If applicants elect either Group III or Group VIII, this application contains claims directed to the following patentably distinct species of the claimed invention: antioxidative factor selected from superoxide dismutase, catalase or peroxidases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 3 is generic.

If applicants elect either Group IV or Group IX, this application contains claims directed to the following patentably distinct species of the claimed invention: lysosomal factor selected from alpha-mannosidase, beta-galactosidase, N-acetyl-beta-glucosaminidase, N-acetyl-beta-galactosaminidase, and lipase.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 3 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for any other group set forth above and the search for each Group is not co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
1635

Scott D. Priebe

SCOTT D. PRIEBE, PH D
PRIMARY EXAMINER